

REMARKS

I. Status of the Claims

Claims 1-101 were filed with the application. Claims 1-58, 63-69 and 71-101 have been withdrawn from consideration and are hereby canceled. Thus, claims 59-62 and 70 are under consideration and have been examined. Claim 60 is now canceled, and claims 59, 62 and 70 are amended. Thus, claims 59, 61, 62 and 70 are presented for reconsideration.

Claim 70 is objected to, claims 59-62 and 70 stand rejected under 35 U.S.C. §112, second paragraph and under 35 U.S.C. §102. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Objection

The examiner has objected to claim 70 as lacking "a" before "cardiac disease." An amendment is offered addressing the objection.

III. Rejections Under 35 U.S.C. §112, Second Paragraph

The examiner has rejected claims 59-62 under §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter.

The examiner again objects to use of the word "modulation" as not defining whether the regulation is up or down. As argued previously, this objection is believed to be improper. The claims encompass both agonism and antagonism of muscle cell growth; hence the use of the word *modulation* is generic and covers both up- and down-regulation. Thus, there is nothing indefinite about the use of this term in this way.

The examiner argues that up- and down-regulation are “mutually exclusive.” While that may be true, “modulation” is *inclusive* of both, and hence there is no conflict with this use of this term. Moreover, whether agonism and antagonism employ structurally distinct molecules is beside the point, since the term “modulation” is at issue, not the terms agonists and antagonists. In fact, to point this out more clearly, applicants have now presented two separate dependent claims – one to agonists and one to antagonists. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 60 has been canceled, thereby obviating the rejection of that claim. To the extent that amended claim 59, which now carries the similar “in a human” recitation, is implicated, applicants submit that the rejection is improper. There is nothing indefinite with regard to the claim being generic to, and hence encompassing both of, endogenous and transplanted cells. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 70 is rejected over the term “pharmaceutical agent.” Applicants have amended claim 70 to clarify that the intended pharmaceutical agent is a second agent that treats cardiac disease, administered in addition to the modulator. Reconsideration and withdrawal of the rejection is respectfully requested.

IV. Rejection Under 35 U.S.C. §102

A. Maintained Rejections

Claims 59-62 are again rejected under 35 U.S.C. §102(a) as being anticipated by Fuentes *et al.* (July 1, 2000). Applicants previously submitted an Inventors’ Declaration under 37 C.F.R. §1.131 to swear behind this reference. The examiner alleges that only unsigned declarations

were submitted. This is not true, as illustrated by the attached materials, which were submitted on July 1, 2003.

Claims 59-62 are again rejected under 35 U.S.C. §102(a) as being anticipated by Rothermel *et al.* (2000). In response, applicants submitted an Inventor's Declaration under 37 C.F.R. §1.132, explaining that the authors of the paper are the current inventors, and that no other authors listed on the papers contributed inventively to the presently claimed invention. The examiner alleges that only unsigned declarations were submitted. This is not true, as illustrated by the attached materials, which were submitted on July 1, 2003.

B. New Rejections

Claims 59, 60 and 70 are rejected as anticipated by (i) Chin *et al.* in view of Rothermel *et al.*, and (ii) Sussman *et al.* in view of Yang *et al.* Applicants traverse.

First, it is pointed out that the claims as amended now recite administration of the modulator to humans. Therefore, the anticipation rejections are overcome as Chin only teaches administration to rats, and Sussman only teaches administration to mice.

Second, as the only remaining rejection available over the Chin and Sussman references would be under §103, applicants further submit that neither Rothermel nor Yang are available for combination with Chin and Sussman. The Rule 131 affidavit (previously submitted on July 1, 2003) has established an invention date prior to the publication of Yang, removing this as "prior" art. The Rule 132 affidavit established that Rothermel is not "by another," and hence unavailable as a reference against the instant claims.

Third, applicants also point out that the claims have been amended to recite the preliminary steps of (a) identifying a human subject in need of muscle cell growth modulation;

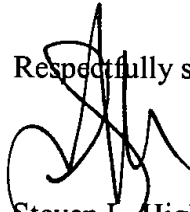
and (b) selecting a small molecule modulator of MCIP1 expression. The Chin and Sussman references are completely silent on the link between MCIP1 expression and muscle cell growth – in fact, these elements are not even mentioned in the references. As such, it would have been impossible for one of skill in the art, viewing either Chin or Sussman, to derive the motivation necessary to modify the prior art teachings so as to arrive at the presently claimed invention. As is well known, “Obviousness cannot be predicated on what is unknown.” *In re Spormann*, 150 USPQ 449 (CCPA 1966).

Applicants submit that, as amended, the present claims clearly are not anticipated by the cited references, nor are they presaged in any fashion that would support an obviousness rejection. Reconsideration and withdrawal of the rejections is therefore respectfully requested.

V. **Conclusion**

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to this effect is earnestly solicited. Should Examiner Liu have any questions regarding this response, he is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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